Exhibit A

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 22-513-RGA
	)	
TEVA PHARMACEUTICALS INC. and TEVA PHARMACEUTICALS USA, INC.,	)	
	)	
Defendants.	)	

DEFENDANTS' SUR-REPLY BRIEF IN OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE TO FILE FIRST AMENDED COMPLAINT AND TO ADD ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD. AS DEFENDANT

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Dated: July 11, 2023

Teva submits this sur-reply to address three new arguments raised in Otsuka's Reply Brief in Support of its Motion for Leave to File First Amended Complaint and to Add Zhejiang Huahai Pharmaceutical Co., Ltd. as Defendant.

First, Otsuka contends that Huahai's joinder would not substantially delay the case because Huahai "on its own or at Teva's direction" could waive the need for service in China as it did in a handful of prior cases. Reply at 5–6. But in each of the cited cases, Huahai's U.S.-based corporate affiliate, Prinston Pharmaceutical Inc., was already a properly named party to the suit. *See AbbVie, Inc. v. Prinston Pharm. Inc.*, C.A. No. 23-cv-470, D.I. 11 (D. Del. July 5, 2023) (Rule 7.1 corporate disclosure statement disclosing that Huahai owns Prinston Pharmaceutical Inc.); *H. Lundbeck A/S et al. v. Prinston Pharm. Inc.*, No. 18-cv-148, D.I. 17 (D. Del. Apr. 9, 2018) (same); *Astellas Pharma Inc. v. Sandoz Inc.*, No. 20-cv-1589, D.I. 82 (D. Del. Mar. 16, 2021) (same); *Otsuka Pharm. Co., Ltd. v. Prinston Pharm. Inc.*, No. 19-cv-1956, D.I. 11 (D. Del. Mar. 16, 2020) (same); *see also AbbVie v. Prinston Pharm. Inc.*, No. 23-cv-607 (D. Del.) (naming Prinston as defendant); *Mayne Pharma Int'l Pty Ltd. v. Prinston Pharm. Inc.*, No. 19-cv-549 (D. Del.) (same); *Otsuka Pharm. Co., Ltd. v. Prinston Pharm. Inc.*, No. 20-cv-1502 (D. Del.) (same). Here, by contrast, no U.S. affiliate of Huahai could properly be sued, and Teva could in no way "direct" Huahai to waive service.

Second, Otsuka argues that joinder of Huahai is necessary because Teva's productions of Huahai documents to date are purportedly deficient. *See* Reply at 2–3. But the bulk of Otsuka's objections to the scope of Teva's production were raised for the first time in the Reply,[1] and the parties are currently conferring over the appropriate scope of the

[1] The scope of Otsuka's requests for DMF documents have been a moving target throughout discovery. Weeks after the parties agreed that Otsuka was limiting its requests to two categories of DMF-related documents that pertained to the disputed elements of the asserted claims, Otsuka sent a deficiency letter demanding the entire DMF. After Teva expressed its confusion, Otsuka confirmed it was not changing its prior position. *See* Motion Brief, Exhibit C at 17–18, 13 and 12 for history of DMF discovery discussions. Now again, Otsuka seems to be demanding the entire DMF, the bulk of which is irrelevant to the asserted claims.

production. These discovery disputes are the appropriate subject of discovery negotiations with Teva, not grounds for joining Huahai.

Third, unable to cite a single decision in which an unaffiliated API manufacturer was deemed an ANDA "submit[ter]" under 35 U.S.C. § 271(e), Otsuka now asserts that it adequately pleaded *induced* infringement by Huahai under 35 U.S.C. § 271(b). Reply at 9–10. But courts have repeatedly rejected the theory that API manufacturers are liable for inducing submission of an ANDA, and there is no immediacy to any future acts of direct infringement that Huahai may allegedly induce only if and when FDA approves the ANDA and Teva proceeds with importing and commercializing an infringing tolvaptan product. *See, e.g.*, *United Therapeutics Corp. v. Sandoz Inc.*, No. 13-cv-00316-PGS-LHG, D.I. 88 (D.N.J. Mar. 31, 2014). The only case Otsuka cites in support of its inducement theory, *Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc.*, has been effectively narrowed to its facts—*i.e.*, where an API manufacturer consented to joinder in the suit, stipulated to infringement, and was expected to itself import infringing API into the United States, the manufacturer could be included within the scope of an injunction as the "prime mover in the chain of events leading to infringement." 501 F.3d 1263, 1272 (Fed. Cir. 2007). Consistent with party and amicus arguments against the broader joinder of API manufacturers in Hatch-Waxman suits, the Federal Circuit expressly declined to extend *Forest*'s induced-infringement holding to scenarios where the API manufacturer was not "currently liable for infringement" because its only conduct relating to the ANDA was "protected by the safe harbor." *Shire LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1310 (Fed. Cir. 2015); *see also* Br. for Generic Pharm. Ass'n As Amicus Curiae, *Shire LLC v. Amneal Pharms., LLC*, 2014 WL 5835516 (Fed. Cir. Oct. 28, 2014). Here, too, Huahai has not committed any act of infringement, and any future accused conduct that it may allegedly later induce is neither immediate nor concrete.

For these reasons, and those in Teva's Opposition, Otsuka's motion should be denied.

/s/ Karen E. Keller

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